K030131

MAY 2 3 2003

510(k) Summary
for
IsoTis NV OsSatura™ BCP Bone Void Filler

1. SPONSOR

IsoTis NV
Prof. Bronkhorstlaan 10
3723 MB Bilthoven
The Netherlands

Contact Person: E. Schutte
Telephone: +31-(0) 30-2295125
Facsimile: +31-(0) 30-2280255

Date Prepared: April 4, 2003

2. DEVICE NAME

Proprietary Name: OsSatura™ BCP

Common/Usual Name: Bone void filler

Classification Name: Bone void filler (Unclassified)

3. PREDICATE DEVICES

Vitoss™ scaffold Synthetic Cancellous Bone void filler(K994337)
Pro Osteon® 500(R) Resorbable Bone void filler (K980817)

4. DEVICE DESCRIPTION

OsSatura™ BCP is a synthetic, osteoconductive bone void filler, which consists of a biphasic ceramic (e.g., hydroxyapatite/tri-calcium phosphate) scaffold. The interconnected and open porous structure of OsSatura™ BCP is similar in structure to human cancellous bone. OsSatura™ BCP is available as irregular-shaped chips of different sizes.

5. INTENDED USE

OsSatura™ BCP (Biphasic Calcium Phosphate) is bone void filler intended only for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. OsSatura™ BCP is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The OsSatura™ BCP and the predicate devices are all similar in design, materials of construction, and function. The OsSatura™ BCP product and the predicate devices are all made of calcium salts. The proposed and predicate devices are osteoconductive. The OsSatura™ BCP product and all the predicate devices provide an interconnected, porous scaffold and an environment for new bone ingrowth. All of the devices are provided sterile and non-pyrogenic for single patient use. The only difference between the proposed device and the predicate devices is that they are composed of different forms of calcium phosphate salts. These minor differences do not affect safety or effectiveness since they are all resorbable and carry out the same function. The safety and biocompatibility testing performed for calcium phosphates and the long history of safe clinical use for hydroxyapatite and tri-calcium phosphate products support the safe use of OsSatura™ BCP. The hydroxyapatite and tri-calcium phosphate in the OsSatura™ BCP meet the requirements in ASTM F1185-88 and F1088-87. Additionally, testing performed on the proposed device confirmed that OsSatura™ BCP meets the applicable requirements of the FDA guidance documents on bone void fillers.

7. TESTING

Pre-clinical animal data demonstrate that OsSatura™ BCP chips support bone ingrowth into a variety of bony defects. Biocompatibility, extensive bench and animal testing using OsSatura™ BCP have been successfully performed to confirm that the device is degraded and resorbed over time and allows bone ingrowth.

Calcium-based ceramic materials, including hydroxyapatite and tri-calcium phosphate, have been used in clinical practice for more than 25 years with no remarkable safety issues. The devices to which OsSatura™ BCP claims substantial equivalence, Pro Osteon 500(R) and Vitoss scaffold, have been used safely for many years in the clinical environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

IsoTis NV
c/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K030131
Trade/Device Name: OsSatura™ BCP (Bi-Calcium Phosphate) Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: April 9, 2003
Received: April 10, 2003

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4660. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030131

510(k) Number (if known): K030131

Device Name: OsSatura™ BCP Bone Void Filler

Indications for Use:

OsSatura™ BCP (Biphasic Calcium Phosphate) is bone void filler intended only for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. OsSatura™ BCP is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced by bone during the healing process.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030131

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)